


Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 25 May 2022



Matthew O'Mullane
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 148 on 1 June 2022. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the food product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (3) For the purposes of this clause:
transition period means the period commencing on the variation's date of commencement and ending 36 months after the date of commencement.

Schedule

Standard 1.1.2 Definitions used throughout the Code

[1.1] Subsection 1.1.2—2(3)

Insert:

very low energy diet means a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label.

very low energy food means a food for special medical purposes produced for consumption as part of a *very low energy diet.

[1.2] Subsection 1.1.2—5(2)

Repeal the subsection, substitute:

- (2) Despite subsection (1), a food is not **food for special medical purposes** if it is:
 - (a) an infant formula product; or
 - (b) a food specially formulated for the dietary management of overweight and obesity and which is not a *very low energy food.

Standard 2.9.5 Food for Special Medical Purposes

[2.1] Section 2.9.5—2 (Note 1)

Omit all the words after “a food is not **food for special medical purposes** if it is”, substitute:

- (a) an infant formula product; or
- (b) a food specially formulated for the dietary management of overweight and obesity and which is not a *very low energy food.

[2.2] Section 2.9.5—2 (after Note 3)

Insert:

Note 4 In this Code (see section 1.1.2—2):

very low energy diet means a range of food for special medical purposes specially formulated for the

dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label.

very low energy food means a food for special medical purposes produced for consumption as part of a *very low energy diet.

[2.3] **After subsection 2.9.5—7(2)**

Insert:

- (3) Subsection (1) does not apply to a *very low energy food.

[2.4] **Subsection 2.9.5—9(2)**

Repeal the subsection, substitute:

- (2) The label for a food for special medical purposes that is a *very low energy food must also state the recommended daily quantity of all very low energy foods to be consumed in order to provide the sole source of nutrition.

- (3) The label must comply with Division 6 of Standard 1.2.1.

[2.5] **Subparagraph 2.9.5—10(1)(g)(ii)**

Omit “(if applicable):”, substitute “(if applicable), and the food is not a *very low energy food:”

[2.6] **Sub-subparagraph 2.9.5—10(1)(g)(ii)(B)**

Omit “appropriate.”, substitute “appropriate;”

[2.7] **After paragraph 2.9.5—10(1)(g)**

Add

- (h) if the food is a *very low energy food:
- (i) a statement to the effect that it is important to maintain adequate daily fluid intake while using the food; and
 - (ii) a statement to the effect that the food is not recommended for pregnant, nursing, or lactating women or use by infants, children, adolescents and elderly, other than under medical supervision; and
 - (iii) a statement indicating that the food is suitable for use as a sole source of nutrition when consumed according to the directions for use on the label.

[2.8] **Section 2.9.5—13**

Repeal the section, substitute:

2.9.5—13 Nutrition information—food for special medical purposes

- (1) For paragraph 2.9.5—9(1)(h), the nutrition information required for a food that is not a *very low energy food is the following, expressed per given amount of the food:
- (a) the minimum or *average energy content; and
 - (b) the minimum amount or *average quantity of:
 - (i) protein, fat and carbohydrate; and
 - (ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and
 - (iii) any substance listed in the table to section S29—20 that has been *used as a nutritive substance in the food; and
 - (iv) subject to paragraph 2.9.5—9(1)(i), any other substance in respect of which a *nutrition content claim has been made.
- (2) For paragraph 2.9.5—9(1)(h), the nutrition information required for a food that is a *very low energy food is the following:
- (a) the *average quantity of that food per serving; and
 - (b) the *average energy content per serving; and

- (c) the minimum amount or average quantity per serving of:
 - (i) protein, fat and carbohydrate; and
 - (ii) linoleic acid and α -linolenic acid; and
 - (iii) any substance listed in the table to section S29—22 that has been *used as a nutritive substance in the food; and
 - (iv) any other vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and
 - (v) subject to paragraph 2.9.5—9(1)(i), any other substance in respect of which a *nutrition content claim has been made.

[2.9] **After section 2.9.5—17**

Insert:

Division 5 Very Low Energy Diets

2.9.5—18 Compositional requirements for very low energy diets

- (1) A *very low energy food must, when consumed according to the manufacturer's directions for use, result in a diet that:
 - (a) has an *average energy content of no less than 1880 kJ/day and no more than 3345 kJ/day; and
 - (b) contains not less than 50 g of *available carbohydrates present within the average energy content required by paragraph (a); and
 - (c) contains not less than 50 g protein per day with a nutritional quality equivalent to a protein digestibility corrected amino acid score of 1, present within the average energy content required by paragraph (a); and
 - (d) contains within the average energy content required by paragraph (a) not less than:
 - (i) 3 g of linoleic acid; and
 - (ii) 0.5 g of α -linolenic acid; and
 - (e) has a ratio of linoleic acid to α -linolenic acid of between 5 and 15; and
 - (f) contains not less than the minimum amount per daily intake, as specified in column 2 of the table to section S29—22, of each nutrient listed in Column 1 of that table.
- (2) Despite subsection 2.9.5—6(2), L-amino acids listed in Column 2 of the table to section S29—20 may be added to a *very low energy food only in an amount necessary to improve protein quality.
- (3) For this section, **protein digestibility corrected amino acid score** means the score calculated and expressed in accordance with the method referred to on page 23 of the Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, Food and Agriculture Organisation of the United Nations, Rome, 1991.

2.9.5—19 Prohibition on health claims in relation to very low energy foods

A *health claim must not be made about a *very low energy food.

Standard 2.9.6 – Transitional standard for special purpose foods (including amino acid modified foods)

[3.1] **After subsection 2.9.6—3(3)**

Repeal the Note, substitute:

- (4) A provision of this Standard ceases to have effect in relation to a *very low energy food 3 years after the commencement of the *Food Standards (Application A1230 – Very Low Energy Diets (VLED)) Variation*.

Schedule 29 Special Purpose Foods

[4.1] **After section S29—21**

Insert:

S29—22 Nutritional content requirements for a very low energy diet

For paragraph 2.9.5—18(1)(f), the table is:

Amounts of nutrients in a very low energy diet	
Column 1	Column 2
<i>Nutrient</i>	<i>Minimum amount per daily intake</i>
Vitamins	
Vitamin A	600 µg retinol equivalents ¹
Vitamin D	2.5 µg
Vitamin E	10 mg α-tocopherol equivalents ²
Vitamin C	30 mg
Vitamin B ₆	2 mg
Vitamin B ₁₂	1 µg
Niacin	11 mg niacin equivalents ³
Riboflavin	1.2 mg
Thiamin	0.8 mg
Folic Acid	200 µg
Minerals	
Calcium	500 mg
Phosphorus	500 mg
Iron	16 mg
Iodine	140 µg
Magnesium	350 mg
Copper	1.5 mg
Zinc	6 mg
Potassium	1.6 g
Sodium	1 g

Note 1 See paragraph 1.1.2—14(3)(a).

Note 2 See paragraph 1.1.2—14(3)(c).

Note 3 For niacin, add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.